CALGB 40503 REGISTRATION WORKSHEET

Endocrine Therapy in Combination with Anti-VEGF Therapy: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy plus Bevacizumab (NSC 704865; IND 7921) for Women with Hormone Receptor-Positive Advanced Breast Cancer

DRAFT

Lead Institution _____ Physician of Record _____

Inst/ Affiliate _____ Participating Group _____

(If the patient has been on a previous CALGB study, specify) CALGB Patient ID ☐☐☐☐☐☐

Protocol Administration

IRB Approval Date ☐☐/☐☐/☐☐☐☐ (M M / D D / Y Y Y Y)

Date Informed Consent Signed ☐☐/☐☐/☐☐☐☐

Projected Start Date of Treatment ☐☐/☐☐/☐☐☐☐

HIPAA Authorization Date ☐☐/☐☐/☐☐☐☐

Contact person at Institution _____

Phone (_____)_____ - _____

FAX (_____)_____ - _____

Patient Demographics/Pre-Treatment Characteristics

Patient Initials ☐, ☐ ☐ (Last, First Middle)

Patient Social Security Number ☐☐☐ - ☐☐ - ☐☐☐☐

Patient's date of birth ☐☐/☐☐/☐☐☐☐ (M M / D D / Y Y Y Y)

Patient Hospital No. ☐☐☐☐☐☐☐☐☐☐ **Gender** ☐ Male ☐ Female

Race *(Mark all that apply)*

☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American

☐ Native Hawaiian or Other Pacific Islander ☐ Unknown ☐ White

Ethnicity *(Mark one)* ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Performance Status ☐ *(ECOG/Zubrod scale)* Height ☐☐☐ *cm* Weight ☐☐☐ *kg* Body Surface Area ☐.☐☐ m^2

Administration (Method of Payment USA only) *(Mark one)*

☐ Medicaid ☐ Medicaid and Medicare ☐ Medicare

☐ Medicare and Private Insurance ☐ Military sponsored (including CHAMPUS and TRICARE) ☐ No means of payment (no insurance)

☐ Other ☐ Private Insurance (Aetna, Blue Cross, Kaiser Permanente, and employer-sponsored insurers)

☐ Self Pay (no insurance) ☐ Unknown ☐ Veterans Sponsored

Patient Zip Code ☐☐☐☐☐ - ☐☐☐☐ Country of Residence *(If not USA)* _____

Certification Of Eligibility

In the opinion of the investigator, is the patient eligible? ☐ No ☐ Yes

Protocol Design

Stratification Factors:

Date of last menstrual cycle ☐☐/☐☐/☐☐☐☐ (M M / D D / Y Y Y Y)

Planned endocrine therapy ☐ Letrozole ☐ Tamoxifen

Disease Free Interval (months from initial diagnosis to first progression) ☐ ≤ 24 months ☐ > 24 months

Is Measurable Disease present? ☐ No ☐ Yes

Assigned Treatment Arm: Kit Number ☐☐☐☐☐☐☐☐

Initial Patient Consent For Specimen Use

Patient's Initial Consent given for:

1. Specimen use for research on the patient's cancer? (150605) ☐ No ☐ Yes
2. Specimen use for genetic research relating to the study treatment? (60605) ☐ No ☐ Yes
3. Specimen kept for future use in research to learn about, prevent, or treat cancer? ☐ No ☐ Yes
4. Specimen(s) may be kept for use in research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease)? ☐ No ☐ Yes
5. Someone may contact me in the future to ask me to take part in more research. ☐ No ☐ Yes

Registration Information

CALGB Patient ID ☐☐☐☐☐☐

Participating Group Patient ID ☐☐☐☐☐☐☐☐

Registration Date ☐☐/☐☐/☐☐☐☐ (M M / D D / Y Y Y Y)

Registrar's Signature _____